IN THE UNITED STATES PATENT AND TRADEMARK OFFICE

Applicants: Michael BUCHANAN et al

Serial No.: New

Filing Date: April 9, 2001

For: USE OF 13-HODE AS A REGULATOR OF VASCULAR

BIOCOMPATIBILITY AND AN INHIBITOR OF CELL HYPERPLASIA

PRELIMINARY AMENDMENT

Assistant Commissioner of Patents Washington, D.C. 20231

Sir:

Prior to initial examination, please amend the above-identified application as follows:

IN THE CLAIMS

Please amend claims 12, 13, 16, 21-23, 27, 28 and 30-32 as follows:

- 12. (amended) The method of claim 10, wherein the omega-3 fatty acid is selected from the group consisting of EPA, DHA, a derivative of EPA and a derivative of DHA.
- 13. (amended) The method of claim 10, wherein the omega-3 fatty acid is ethyl-EPA or ethyl-DHA.
- 16. (amended) The pharmaceutical composition of claim 14 wherein the daily dose of 13-HODE is equal to or less than 100 mg.

- 21. (amended) The pharmaceutical composition of claim 14, wherein the composition is administered in the form selected from the group consisting of tablets, dragees, capsules, granules, solutions, suspensions and lyophilized compositions.
- 22. (amended) The pharmaceutical composition of claim 14 wherein the composition further comprises a fat-soluble antioxidant selected from the group consisting of ascorbyl palmitate, tocopherols, and ascorbic acid in the presence of lecithin.
- 23. (amended) The pharmaceutical composition of claim 14 wherein the composition further comprises an additive selected from the group consisting of aggregants, disaggregants, osmotic pressure regulating salts, buffers, sweeteners, and coloring agents.
- 27. (amended) The use of the pharmaceutical composition of claim 14 to treat:
 - (a) cardiovascular or cerebrovascular disease
 - (b) inflammatory or autoimmune disease
 - (c) infection with bacteria, viruses, fungi, or protozoa,
 - (d) respiratory disease
 - (e) gastrointestinal disease
 - (f) renal or urinary tract disease
 - (q) skin disease
 - (h) neurological or psychiatric disease
 - (i) disease of the reproductive system
 - (i) diabetes, syndrome A or any complication of diabetes

- 28. (amended) The use of the pharmaceutical composition of claim 14 to treat a disease or condition associated with overactive protein kinases.
- 30. (amended) The use of the pharmaceutical composition of claim 14 to treat a disease or condition where endothelial function is disordered.
- 31. (amended) The use of the pharmaceutical composition of claim 14 to treat cancer or the metastatic spread of cancer.
- 32. (amended) The use of the pharmaceutical composition of claim 14 to prevent cancer or the metastatic spread of cancer.

REMARKS

The foregoing Preliminary Amendment is requested in order to delete the multiple dependent claims and avoid paying the multiple dependent claims fee.

Attached hereto is a marked-up version of the changes made to the specification and claims by the current amendment. The attached page is captioned "VERSION WITH MARKINGS TO SHOW_CHANGES MADE."

Early action on the merits is respectfully requested.

Respectfully submitted,

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VERSION WITH MARKINGS TO SHOW CHANGES MADE

IN THE CLAIMS

- 12. (amended) The method of claim 10 [or 11], wherein the omega-3 fatty acid is selected from the group consisting of EPA, DHA, a derivative of EPA and a derivative of DHA.
- 13. (amended) The method of claim 10 [or 11], wherein the omega-3 fatty acid is ethyl-EPA or ethyl-DHA.
- 16. (amended) The pharmaceutical composition of claim 14 [or 15] wherein the daily dose of 13-HODE is equal to or less than 100 mg.
- 21. (amended) The pharmaceutical composition of claim 14 [or 15], wherein the composition is administered in the form selected from the group consisting of tablets, dragees, capsules, granules, solutions, suspensions and lyophilized compositions.
- 22. (amended) The pharmaceutical composition of claim 14 [or 15] wherein the composition further comprises a fat-soluble antioxidant selected from the group consisting of ascorbyl palmitate, tocopherols, and ascorbic acid in the presence of legithin.
- 23. (amended) The pharmaceutical composition of claim 14 [or 15] wherein the composition further comprises an additive selected from the group consisting of aggregants, disaggregants, osmotic pressure regulating salts, buffers, sweeteners, and coloring agents.

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- 27. (amended) The use of the pharmaceutical composition of claim 14 [, 15, 16, 17, 18, 19, 20, 21, 22, 23, 24, 25 or 26] to treat:
 - (a) cardiovascular or cerebrovascular disease
 - (b) inflammatory or autoimmune disease
 - (c) infection with bacteria, viruses, fungi, or protozoa,
 - (d) respiratory disease
 - (e) gastrointestinal disease
 - (f) renal or urinary tract disease
 - (g) skin disease
 - (h) neurological or psychiatric disease
 - (i) disease of the reproductive system
 - (j) diabetes, syndrome A or any complication of diabetes
- 28. (amended) The use of the pharmaceutical composition of claim 14 [, 15, 16, 17, 18, 19, 20, 21, 22, 23, 24, 25 or 26] to treat a disease or condition associated with overactive protein kinases.
- 30. (amended) The use of the pharmaceutical composition of claim 14 [, 15, 16, 17, 18, 19, 20, 21, 22, 23, 24, 25 or 26] to treat a disease or condition where endothelial function is disordered.
- 31. (amended) The use of the pharmaceutical composition of claim 14 [, 15, 16, 17, 18, 19, 20, 21, 22 or 23] to treat cancer or the metastatic spread of cancer.
- 32. (amended) The use of the pharmaceutical composition of claim 14 [, 15, 16, 17, 18, 19, 20, 21, 22 or 23] to prevent cancer or the metastatic spread of cancer.